

## **REMARKS**

### **Summary of Amendment and Status of Claims**

Upon entry of this amendment, claims 1-10 will be amended. Claims 1-10 are all the claims pending in the application. Claims 1-10 are rejected.

Applicants note that the amendments to claims 1-10 were made to even more clearly recite the claimed subject matter. Claims 1-10 have been amended to recite a “method for treating overactive bladder”. Support for the amendments to claims 1-10 may be found throughout the originally filed specification, for example, at pages 6-7 and 9. The present amendment merely clarifies that the term “remedy” means a “method for treating overactive bladder.” As stated at the sentence bridging pages 7-8 of the original specification, “the active ingredient of the present invention is useful, in addition to treatment of diabetes, as an agent for prevention and treatment of other diseases”, and at page 9, lines 16-18 that “the active ingredient of the present invention has been found to be useful as a remedy for overactive bladder which is a new use.”

No new matter is added.

### **Information Disclosure Statements**

Applicants thank the Examiner for acknowledging receipt of the Information Disclosure Statements filed May 9, 2005, by returning initialed Forms PTO SB/08 therein.

### **Claim to Priority**

Applicants note that the Examiner has not acknowledged the claim of priority to Japanese Application No. 2002-323792 filed November 7, 2002.

Accordingly, Applicants respectfully request acknowledgement by the Examiner of the claim to priority.

**Nonstatutory Obviousness-Type Double-Patenting**

Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6-12 of U.S. Patent 6,346,532 (“the ‘532 patent”). The Office Action asserts that claim 6 of the ‘532 patent is drawn in part to the instant claimed compound: (R)-2-(2-aminothiazol-4-yl)-4-[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide. Furthermore, the Office Action asserts that “[w]ith respect to the instant claims, no patentable weight is being given to the intended use (i.e. overactive bladder, urinary incontinence, urinary urgency, and pollakiuria) of the instant claims as these claims are construed as directed to a composition.” (See page 3 of the Office Action).

In response, Applicants note that the ‘532 patent is directed to amide derivatives represented by general formula (I), and that are disclosed to be useful as a diabetes remedy. (See abstract of the ‘532 patent). The amide derivatives of the ‘532 patent are disclosed to accelerate insulin secretion and enhance insulin sensitivity, along with having antiobesity and antihyperlipidemic action. (See abstract of the ‘532 patent). There is nothing in the ‘532 patent that teaches or suggests the presently claimed method of treating overactive bladder by administering acetic acid anilide of the present invention. In fact, the ‘532 patent teaches use of the disclosed amide derivatives for the prevention and therapy of “other diseases [such as]...reducing the symptoms of obesity and hyperlip[d]emia such as ischemic coronay diseases such as arteriosclerosis, myocardial infarction, angina pectoris,...cerebral arteriosclerosis such as cerebral infarction,...or aneurysm”. (See column 10, lines 23-29 of the ‘532 patent).

The claimed method of treating overactive bladder was not within common knowledge or common sense of one of ordinary skill, and it would not have been obvious to one of ordinary skill in the art at the time the invention was made to obtain the claimed method of treating overactive bladder comprising administering acetic acid anilide compound.

Accordingly, reconsideration and withdrawal of the rejection on the ground of nonstatutory obviousness-type double patenting is respectfully requested.

**Provisional Nonstatutory Obviousness-Type Double-Patenting**

Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending U.S. Patent Application No. 10/494,018 (“the ‘018 application”). The Office Action asserts that “[t]he crystal forms (*e.g.*  $\alpha$ -form crystal,  $\beta$ -form crystal, and crystal form) of (R)-2-(2-aminothiazol-4-yl)-4-[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide as recited in the reference claims are reasonably construed to be obvious variants of (R)-2-(2-aminothiazol-4-yl)-4-[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide in the absence of evidence to the contrary.” Furthermore, the Office Action asserts that “no patentable weight is being given to the intended use (*i.e.* overactive bladder, urinary incontinence, urinary urgency, and pollakiuria) of the instant claims as these claims are construed as directed to a composition.”

Similar to the ‘532 patent, the ‘018 application is directed to a remedy for diabetes using an  $\alpha$ - or  $\beta$ -form crystal of an acetanilide. (See paragraphs [0001] and [0047] of the ‘018 application). As discussed above, the claimed method for treating overactive bladder was not within the common knowledge or common sense of one of ordinary skill in the art so that it was not obvious for a skilled artisan at the time the invention was made to obtain the claimed method.

Accordingly, reconsideration and withdrawal of the provisional rejection on the ground of nonstatutory obviousness-type double patenting is respectfully requested.

**Rejections Under §102**

Claims 1-10 are rejected under 35 USC §102(b) as being anticipated by Maruyama *et al.* (WO99/20607; “Maruyama”). The Office Action asserts that Maruyama teaches the instant claimed composition comprising compound (R)-2-(2-aminothiazol-4-yl)-4'[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide and the intended use (*e.g.* overactive bladder, urinary urgency, urinary incontinence, and pollakiuria) is not weighed in the interpretation of composition claims.

Applicants note Maruyama corresponds to the '532 patent and the rejection based on Maruyama will be addressed by referring to the '532 patent. As discussed above, the '532 patent is directed to amide derivatives represented by general formula (I), and that are disclosed to be useful as a diabetes remedy. (See abstract of the '532 patent).

The '532 patent does not explicitly or inherently disclose the claimed method for treating overactive bladder comprising administering (R)-2-(2-aminothiazol-4-yl)-4'[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide or a salt thereof as an active ingredient.

Accordingly, reconsideration and withdrawal of the rejection under §102(b) is respectfully requested.

**CONCLUSION**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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